



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ) Art Unit: 1643  
CLASSEN, John B. ) Examiner: B. BRUMBACK  
Appln. No.: 08/591,651 ) Washington, D.C.  
Date Filed: February 12, 1996 ) December 12, 2002  
For: METHOD AND COMPOSITION FOR ) DOCKET: CLASSEN=1A  
AN EARLY VACCINE TO PROTECT )  
AGAINST BOTH COMMON... ) Confirmation No.: 941

COMMUNICATION

Honorable Commissioner for Patents  
Washington, D.C. 20231

S i r:

It has come to our attention that in the Appellant's Brief filed November 5, 2002, a certain Table did not print properly, even though the corresponding table (in the October 18 declaration did print properly.

The problem appeared in Table 2A, item 3, "BCG-China", which appears at the bottom of page 55 of the brief.

To correct the problem, we enclose, in triplicate, pages 55 and 55a. Item 3 has been moved from page 55 to page 55a, and the missing text restored. (Compare this text to page 23 of the October 18 declaration.) These should be inserted into the previously filed copies of the Appellant's Brief. If the Examiner would prefer that we submit a corrected Appellant's Brief in triplicate, she should so advise counsel.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant(s)

By:   
Iver P. Cooper  
Registration No. 28,005

624 Ninth Street, NW  
Washington, D.C. 20001  
Telephone No.: (202) 628-5197  
Facsimile No.: (202) 737-3528  
IPC:lms  
G:\ipc\A-c\clas\classenla\PTO COMMUNICATION.WPD

RECEIVED  
DEC 13 2002  
TECH CENTER 1600/2900

<p>2. all immunogens, Global LaPorte (cited by PIDJ)</p>	<p>According to PIDJ, LaPorte presented data "demonstrating a global increase in the incidence of type 1 diabetes mellitus that cannot be explained by improved surveillance." However, PIDJ continues, "the incidence of type 1 diabetes has increased in countries with and without introductions of new vaccines into the immunization schedule." (219, col. 2,- 220, col. 1)</p> <p>PIDJ does not cite any LaPorte publication as related to this passage. A MEDLINE search revealed Karvonen, et al., "Incidence of Childhood Type 1 Diabetes Worldwide," Diabetes Care, 23: 1516-26 (Oct. 2000). While this article acknowledges that "the incidence of type 1 diabetes appears to be increasing in almost all populations worldwide", it refused to rule out a surveillance effect: Whether this is a true increase resulting from changing lifestyle factors or is simply an improvement in case ascertainment is currently impossible to determine." (1524, col. 2).</p> <p>Also, LaPorte has not presented any of the particulars of this data, i.e., which vaccines were introduced in which countries at which times, what was the immunization protocol, and what was the rate of incidence of diabetes before and after these introductions or protocol changes. PIDJ does not consider whether there are differences in the rate of increase depending on whether a new vaccine had been introduced, or whether changes in old vaccines played any role. A new vaccine administered at birth could decrease incidence, shifting an old vaccine from birth to three months could increase it. Consequently, it is impossible to ascertain the merits of the conclusion stated by PIDJ. <b>This passage in PIDJ is not entitled to any weight.</b></p>
--	---

3. BCG-China

LaPorte (cited by PIDJ)

PIDJ declares that "Because BCG vaccine is given to almost all infants at birth in China, Dr. LaPorte noted that the marked variability in the incidence of type 1 diabetes within China is additional evidence against a major effect of BCG on diabetes incidence." (219, col. 2)

PIDJ does not cite any LaPorte publication as related to this passage. A MEDLINE search revealed Yang et al. (LaPorte is a co-author), "Childhood Diabetes in China: enormous variation by place and ethnic group", 21: 525 (1998). This article notes that there is a 12-fold geographic variation and a 6-fold ethnic variation in diabetes incidence in China. It does not make any reference to immunization practices in China.

Even if all Chinese were immunized with BCG at birth, it would not be surprising that there is substantial variation in diabetes incidence in a country with "one-fourth of the world's population, 56 ethnic groups spread over 9.6 million square kilometers, and remarkably different climates, diets and patterns of infectious diseases." Applicant claimed that immunization was a risk factor, not that it was the only risk factor, or even the most important one.

Nonetheless, Applicant thinks it worth pointing out that Yang et al.'s conclusion was that "China has an extremely low **overall** IDDM incidence rate." Perhaps that is the impact of the BCG immunization at birth.